Remarks

In view of the above amendments and the following remarks, reconsideration and allowance of this application are requested. Claims 17-25, 36, 37 and 39 are pending; the two independent claims, claims 17 and 36, have been amended, as has dependent claim 25. Claims 1-16, 26-35 and 38 have been cancelled. Support for the amendments to independent claims 17 and 36 may be found, for example, in the application as filed in Table 1, at page 9. Support for the amendment to dependent claim 25, which is non-substantive in nature, may be found in claim 25 as filed. No new matter has been added.

In the Office Action dated February 9, 2006, the Examiner rejected claims 17-23 and 36-29 under 35 U.S.C. § 103 as being obvious over Grabow et al. (GB 2,293,103). The Examiner based this rejection on the following observation: "As to the defined particle size range, Grabow et al. teach *a bimodal range* similar to that claimed. Optimum suitable ranges may be obtained by routine experimentation, absent a showing of criticality or unexpected results." (emphasis added). Thus, the Examiner bases this rejection on (1) bimodal size distribution taught by Grabow et al. and recited in the unamended claims and (2) the assumption that the compositions of the unamended claims and of Grebow were "the same." As the Examiner concluded: "the claimed properties . . . must also be possessed by the obvious composition, because it is the same as that claimed."

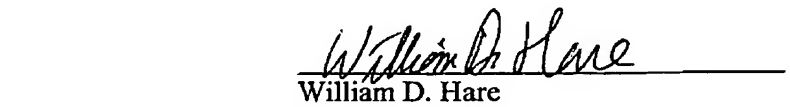
As the Examiner acknowledges, Grabow et al. teaches certain, bare, bimodal distributions of particle size ranges. One of skill in the art would not have been motivated to modify the particle size characteristics to have the particle size distributions as recited in the amended claims; these distributions are not merely bimodal. Rather, as recited in amended claims 17 and 36, the presently–claimed oral dosage forms also require that about 90% of the particles having diameters size less than 220 μm are further characterized in that they have diameters less than about 41 μm, and about 50% of the particles having diameters size less than 220 μm are further characterized in that they have diameters less than about 21 μm.

These further size distribution restrictions, referred to in Applicant's specification as d_{90} and d_{50} values, respectively, see Table 1, are non-obvious. These additional restrictions lead to a heretofore unattainable ability to distinguish formulations exhibiting "large initial release" profiles from those exhibiting lower initial release profiles, even for formulations having similar bimodal particle size distributions. Surprisingly, then, particularly in view of Grebow et al, Applicants' invention thus permits a release profile distinction *between two formulations having similar bimodal distribution* (see, e.g., Examples 1 and 3 of Table 1); by controlling the d_{90} and d_{50} values, Applicants can effect control of release rate profiles while maintaining a desired bimodal distribution.

Conclusion

For the reasons stated above, the Examiner is urged to pass claims 17-25, 36, 37 and 39 to issue. Authorization is hereby given to charge any fees deemed to be due in connection with this Response to Office Action to Deposit Account No. 50-0912.

Respectfully submitted,



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